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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,874	04/25/2007	Dirk Seegert	31304-763.831	8046

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

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03/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,874	SEEGERT ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-7, 12-13) in the reply filed on 12/28/07 is acknowledged. Upon further consideration it was determined that a further restriction of Group I (claims 1-7, 12-13) was required. A restriction on all pending claims 1-13 follows.

Election/Restriction

2. This application is a 371 of PCT/EP04/06787. For applications filed under 371, PCT rules for lack of unity apply.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-7, 12, drawn to a polypeptide dimer comprising two soluble gp130 molecules.

Group II. Claims 8-11, drawn to a nucleic acid encoding a polypeptide dimer comprising two soluble gp130 molecules, a vector, a host cell, and a process for producing the polypeptide.

Group III. Claim 13, drawn to a method of treatment of bone resorption by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group IV. Claim 13, drawn to a method of treatment of hypercalcemia by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group V. Claim 13, drawn to a method of treatment of cachexia by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group VI. Claim 13, drawn to a method of treatment of a tumor by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group VII. Claim 13, drawn to a method of treatment of an autoimmune disease by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group VIII. Claim 13, drawn to a method of treatment of an inflammatory disease by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group IX. Claim 13, drawn to a method of treatment of a bacterial or viral infection by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group X. Claim 13, drawn to a method of prevention of bone resorption by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group XI. Claim 13, drawn to a method of prevention of hypercalcemia by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group XII. Claim 13, drawn to a method of prevention of cachexia by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group XIII. Claim 13, drawn to a method of prevention of a tumor by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group XIV. Claim 13, drawn to a method of prevention of an autoimmune disease by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group XV. Claim 13, drawn to a method of prevention of an inflammatory disease by administering a polypeptide dimer comprising two soluble gp130 molecules.

Group XVI. Claim 13, drawn to a method of prevention of a bacterial or viral infection by administering a polypeptide dimer comprising two soluble gp130 molecules.

NOTE: With respect to claim 13, which embraces a use of a polypeptide dimer comprising two soluble gp130 molecules, there are no provisions for "a use" in the statutes. The Examiner has interpreted the claim as “a method for the treatment” and “a method for the prevention” by using the polypeptide dimer comprising two soluble gp130 molecules Applicants are requested to amend the claims to recite "a process or a method" of using the polypeptide dimer comprising two soluble gp130 molecules,

In view of the improper format for claim 13, the claim has been restricted by interpretation of the intended meaning of the claim.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since EP 1148065 teaches a fusion protein comprising two soluble gp130 molecules, which are PEGylated (see abstract; see page 5, column 7, paragraph [0038]). Since the first claimed invention lacks a special technical feature, the other claimed invention cannot share a special technical feature with the first claimed invention. The invention of Group I is patentably distinct from the invention of Group II because the products of Groups I and II are materially and functionally different products. Furthermore, the inventions of Groups I and II are patentably distinct because the product of Group I can be used in methods that are materially different from the methods in which the invention of Groups II are used, such as antigen in the production of antibodies or in immunochromatography to purify antibodies.

The inventions of Groups III-XVI are independent and distinct, each from the other, because the methods are practiced with different patient populations and have different starting materials, process steps and goals. For example, the only feature in common in inventions VII-VIII is "the method for the treatment of autoimmune disease or inflammatory disease…", which does not constitute the special technical feature lacking from the prior art because these methods can be used with a composition other than the instant product such as glucocorticoids. Furthermore, separate search terms would be required for searching the literature, eg. a search of

the literature for an association of the polypeptide-dimer with inflammation would not necessarily reveal art for an association of the polypeptide-dimer with treatment of a tumor.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Rejoinder under *In re Ochiai, In re Brouwer*

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and classification as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646